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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,219

07/29/2003

Michael P. Schrom

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05/25/2006

FULBRIGHT & JAWORSKI, L.L.P. (ANS)

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SUITE 2800

DALLAS, TX 75201-2784

EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/630,219	Applicant(s) SCHROM ET AL.	
	Examiner Deborah Malamud	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 12-21, 32-39 and 42-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 22-31, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/23/06, 1/25/05, 12/16/04, 12/29/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I (claims 1-11, 22-31 and 40-41 in the reply filed on 28 April 2006 is acknowledged. Claims 12-21, 32-39 and 42-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 28 April 2006.

Specification

2. The disclosure is objected to because of the following informalities: applicant needs to complete the "Cross-reference to related patent documents" section of his application found on page 1 of his specification to indicate the serial numbers of the applications applicant is referring to rather than the attorney docket reference numbers. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4, 7, 10, 22, 29 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the "extrusion material" for each of the layers and the coating are meant to be the same material or a different material.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-4, 6-7, 9-10, 22-23, 26-29, 31 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis et al (U.S. 5,476,495). Regarding claims 1, 4, 7, 10, 22-23, 26-29 and 40, Kordis discloses (col. 13, lines 56-68; Figures 33-38) a process for making a multiple layer mapping probe catheter body (96) for deployment in a region of the heart. In Figure 33, a center tube (106), made of Pebax plastic tubing, is “fastened by clamps 124 to a mandrel (126).” The examiner considers this to be placing an inner layer of extrusion material on a mandrel. A wire holder (128) dispenses signal wires to form a first layer (110) of signal wires (col. 14, lines 7-12), which are then coated with “insulating Teflon plastic tape.” The examiner considers this to be placing at least one conductor coated with a layer of extrusion material on the inner layer of extrusion material. In Figure 36 (col. 14, lines 29-33), “another holder (136) is advanced by the lead screw (130) along the axis of the rotating mandrel. The holder helically wraps metalized plastic material (138) about the second wire layer (112), creating EMI shield layer (116).” The cross-section of the lead in Figure 30 shows a unitary wall, wherein the conductors are within the unitary

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wall. Kordis further discloses (col. 5, lines 22-27; Figures 12 and 13) basket electrodes (26) attached to the lead and in communication with connectors (44) in the handle of the lead.

7. Regarding claims 3, 6, 9 and 31, Kordis discloses that the inner layer, the coating layer and the outer layer are all made from a plastic material (e.g., Pebax or Teflon plastic).

8. Further regarding claim 22, Kordis discloses (col. 13, lines 45-49; Figures 31 and 32) "the signal wires are preferably wound helically along the length of the catheter body." The examiner considers this to be at least one conductor within the unitary wall and spirally wound around the lumen.

9. Claims 4-5, 7-8, 10-11, 22, 24-25 and 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Cimino et al (U.S. 5,857,997). Regarding claims 4, 7, 10, 22 and 40, Cimino discloses (col. 9, lines 57-58; col. 10, lines 4-10) an inner tubular member (25) formed of a thermoplastic elastomer and an outer jacket or coating (26) formed of a thermoplastic polymeric material. Within the inner tubular member are electrical conductors. These layers are formed using (col. 6, lines 62-68) a mandrel or stiffening member. Cimino also discloses the conductors connected to an electrical connector (53; col. 9, lines 29-33) on the proximal end of the handle in Figure 8, and to sensing and ablation electrodes (col. 5, lines 60-68).

10. Regarding claims 5, 8, 11, 24-25 and 41, Cimino discloses (col. 10, lines 38-48) a procedure for forming the catheter (10): "to complete the catheter body member, a heat shrinkable thermoplastic tubular member or sleeve which forms

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the outer jacket (26) is fitted onto the braided and impregnated reinforcing layer (27), and then a heat shrinkable tubular element (not shown) is fitted over the thermoplastic tube forming the outer jacket and the assembly is then heated by hot air to shrink the heat shrinkable tube and press the thermoplastic tube against the exterior of the reinforcing layer to secure the jacket thereto. Upon cooling, the heat shrinkable tube is stripped off and discarded and the catheter is then ground to the desired outer diameter."

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kordis et al (U.S. 5,476,495) in view of Cimino et al (U.S. 5,857,997). Kordis teaches the claimed invention except for the process of using a heat shrink tubing. Cimino however does disclose this in the above-cited paragraphs. Kordis and Cimino both teach catheters for insertion into a patient's heart. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kordis' multilayer catheter with Cimino's heat shrink tubing in order form the lead into a specific shape.

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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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